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Duncan et al.

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(54) **PERCUTANEOUS NEPHROSTOMY PLUG
DELIVERY DEVICE**

USPC 74/422, 89.17–89.19, 498–500; 604/57,
604/60, 61; 294/119.1, 207, 209; 606/213
See application file for complete search history.

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(51) **Int. Cl.**

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ABSTRACT

A device for delivering a percutaneous nephrostomy plug is provided. The device comprises a tubular member configured for insertion into a biological body. The device further comprises a handle coupled to a proximal end of the tubular member. The handle comprises a pusher element, an actuation element, and a transmission. The pusher element is disposed within the tubular member, and is configured to deliver a plug through a distal end of the tubular member. The transmission is coupled to the tubular member and the actuation element, and the transmission is configured to cause a retraction of the tubular member relative to the pusher element in response to a depression of the actuation element. A first depression of the actuation element toward the tubular member urges a partial exposure of the plug. A second depression of the actuation element urges a further exposure of the plug.

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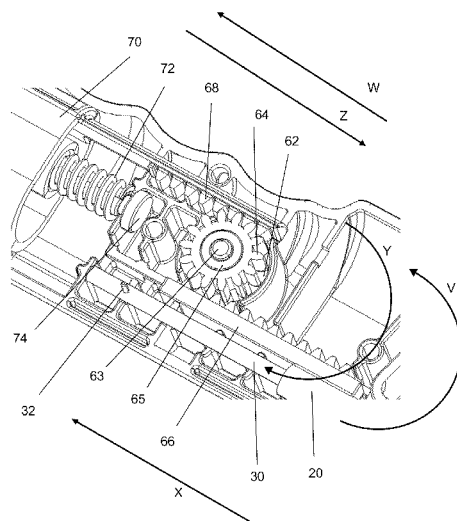
CPC ... **A61B 17/0057** (2013.01); **A61B 2017/00654**
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2017/2923 (2013.01)

USPC **606/213**

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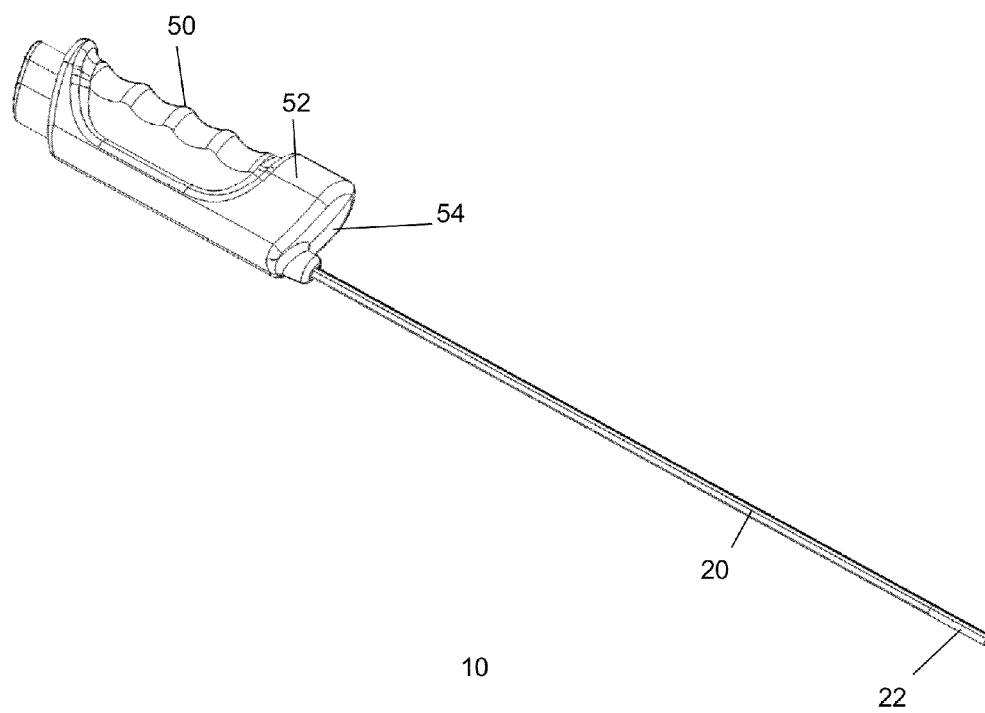


FIG. 1

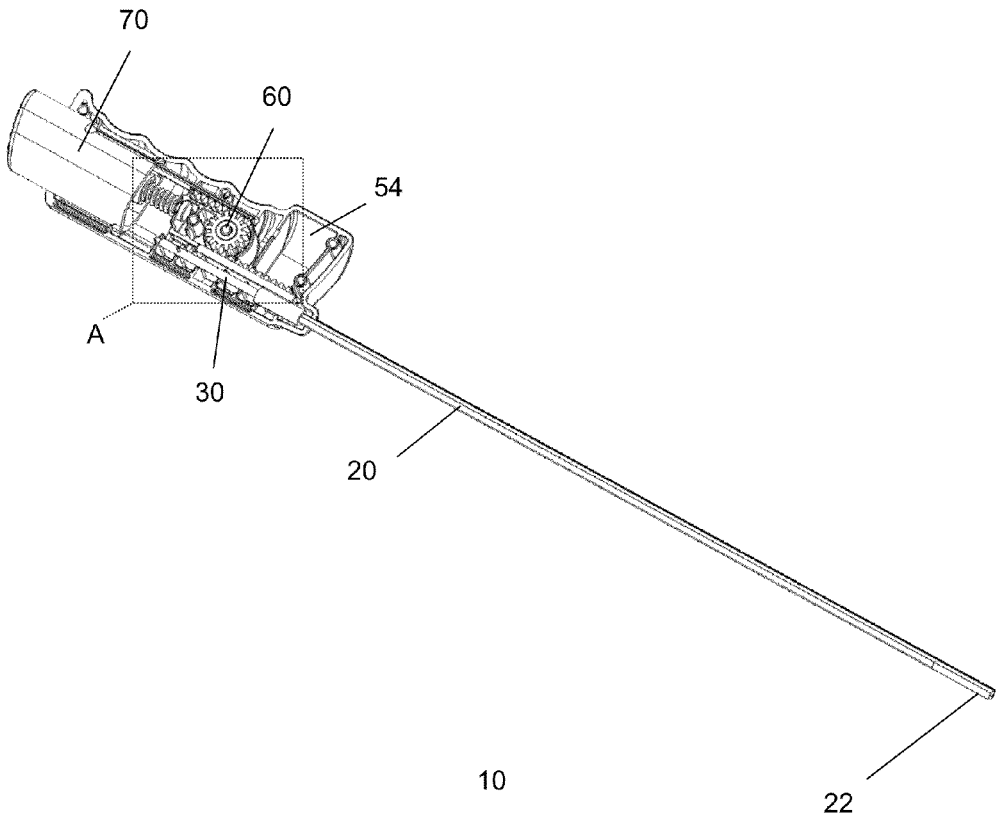


FIG. 2

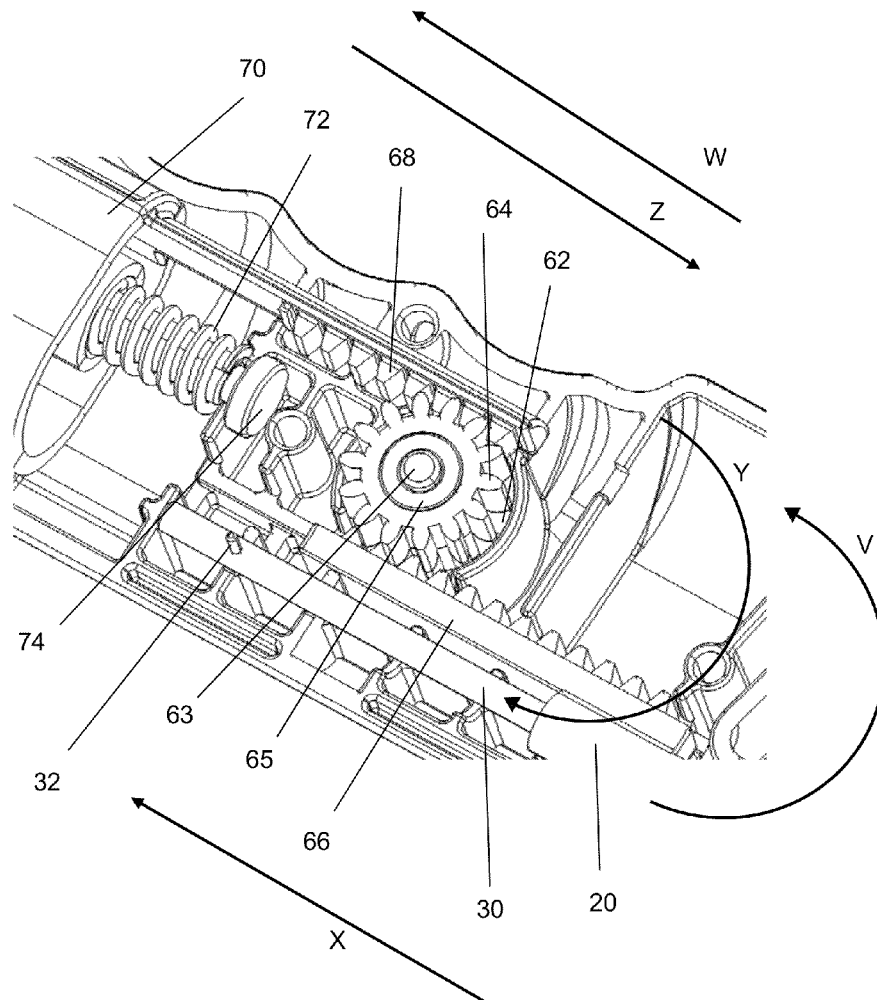


FIG. 2A

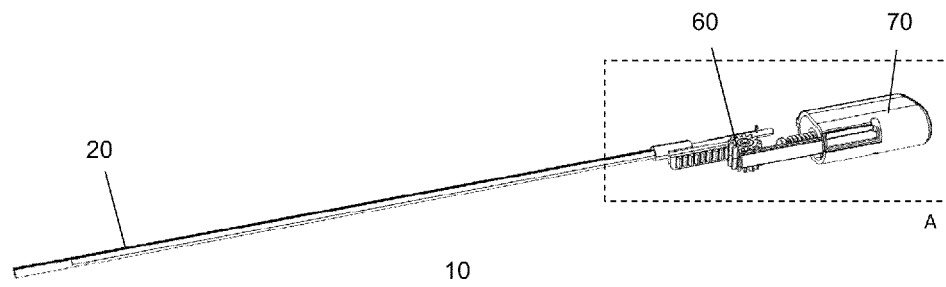


FIG. 3

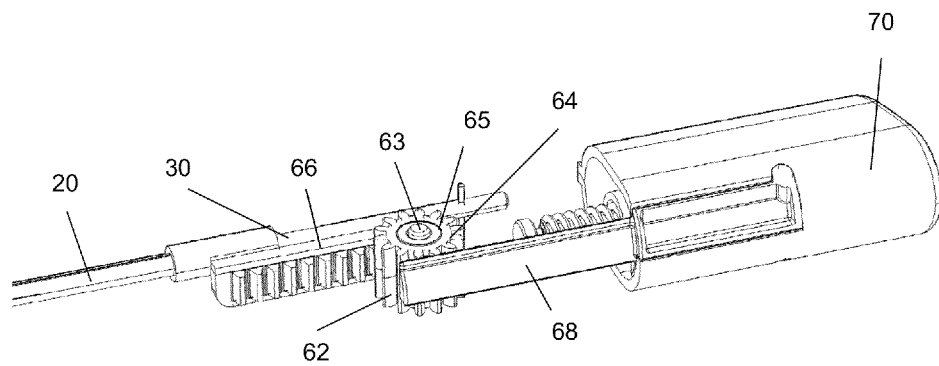
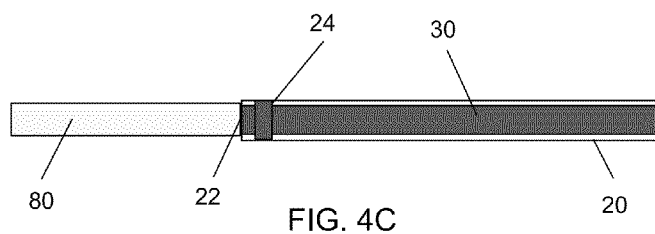
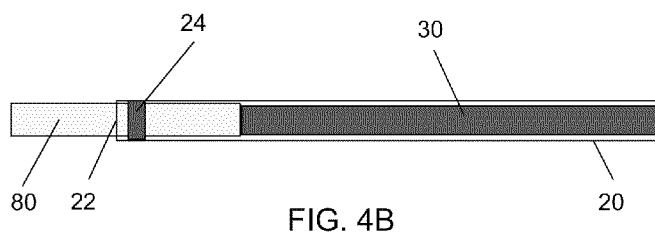
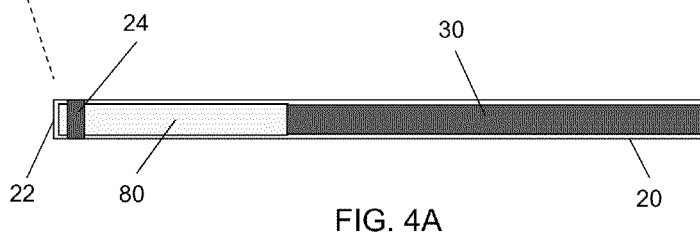
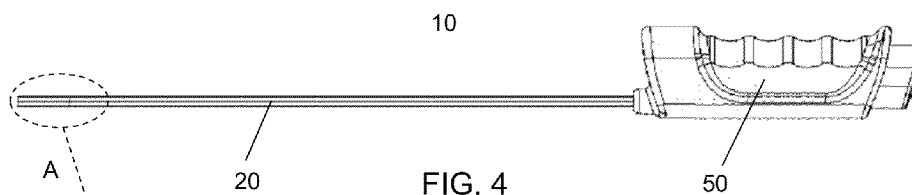


FIG. 3A



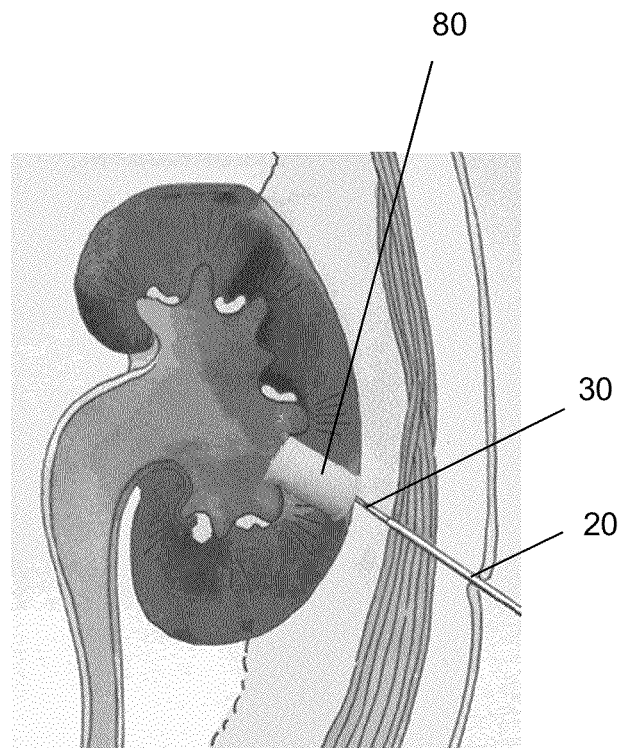


FIG. 5

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PERCUTANEOUS NEPHROSTOMY PLUG DELIVERY DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit under 35 U.S.C. §119(e) of U.S. provisional application 61/539,114, filed on Sep. 26, 2011, entitled "PERCUTANEOUS NEPHROSTOMY PLUG DELIVERY DEVICE," the content of which is incorporated herein by reference for all purposes.

TECHNICAL FIELD

This disclosure relates generally to medical devices and more particularly to devices for delivery of a nephrostomy plug to close a dilated nephrostomy tract in the kidney after a percutaneous nephrolithotomy procedure.

Percutaneous nephrolithotomy (PCNL) is a surgical procedure for removal or treatment of kidney stones through a small incision on the skin. Kidney stones are solid aggregations that form in the kidneys due to crystallization of minerals in the urine. Removal of kidney stones is necessary to relieve pain, bleeding or infections in the urinary tract due to blockages. During a PCNL procedure, the surgeon typically makes a small incision (1-1.5 cm) on the skin of the back of the patient. The surgeon then inserts a needle and a guide wire to create a nephrostomy tract in order to allow insertion of a nephroscope directly into the kidney. A nephroscope is a fiberoptic instrument that facilitates locating kidney stones and removing them through suction. In the case of large stones, an ultrasonic or laser probe may be inserted through the nephroscope to break the large stones into smaller pieces. After stone removal is complete, a nephrostomy tube is typically placed into the kidney and left in the patient for one or more days to drain urine. This may require the patient to stay in the hospital for one or more days for observation.

BRIEF SUMMARY

A first representative embodiment of the disclosure provides a medical device comprising a tubular member with a proximal end and a distal end, the tubular member is configured for insertion into a biological body. The medical device further comprises a handle coupled to the proximal end of the tubular member. The handle comprises a pusher element, an actuation element, and a transmission. The pusher element is disposed within the tubular member; the pusher element is configured to deliver a plug through the distal end of the tubular member. The transmission is coupled to the tubular member and the actuation element; the transmission is configured to cause a retraction of the tubular member relative to the pusher element in response to a depression of the actuation element. A first depression of the actuation element toward the tubular member urges a partial exposure of the plug. A second depression of the actuation element toward the tubular member urges a further exposure of the plug.

A second representative embodiment of the disclosure provides a medical device comprising a tubular member with a proximal end and a distal end, the tubular member is configured for insertion into a biological body. The medical device further comprises a handle coupled to the proximal end of the tubular member. The handle comprises a pusher element, and actuation element, and a transmission. The pusher element is configured to slide within the tubular member to deliver a plug through the distal end of the tubular member. The actuation element comprises a button and a spring coupled to the

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button. The transmission is coupled to the tubular member and the actuation element. The transmission comprises a first rack coupled to the button, a second rack coupled to the tubular member, a first gear engaged with the first rack, and a second gear engaged with the second rack. The second gear is selectively coupled to the first gear; and a roller clutch is coupled to the first gear. A first depression of the button urges a first rotation of the first and second gears in a first direction, causing a retraction of the tubular member relative to the pusher element. Upon release of the button, the first gear rotates in a direction opposite the first direction, but the second gear remains stationary. A second depression of the button urges a second rotation of the first and second gears in the first direction, causing a further retraction of the tubular member relative to the pusher element.

A third representative embodiment of the disclosure is a method for delivering a plug to a biological body. The method includes the step of inserting a distal end of a tubular member into a biological body, where the tubular member contains a plug at the distal end and a pusher element. The method further includes the step of causing a first retraction of the tubular member relative to the pusher element in a proximal direction, urging a partial exposure of the plug within the biological body. The method further includes the step of causing a second retraction of the tubular member relative to the pusher element in a proximal direction, urging a further exposure of the plug within the biological body.

Advantages of the present disclosure will become more apparent to those skilled in the art from the following description of the preferred embodiments of the disclosure that have been shown and described by way of illustration. As will be realized, the disclosed subject matter is capable of other and different embodiments, and its details are capable of modification in various respects. Accordingly, the drawings and description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a device for percutaneous delivery of a nephrostomy plug to the kidney.

FIG. 2 is a perspective view of the device of FIG. 1 with the top half of the handle housing removed to show the mechanism inside.

FIG. 2A is a close-up view of detail A of FIG. 2.

FIG. 3 is a perspective view of the device of FIG. 1 with the handle housing removed.

FIG. 3A is a close-up view of detail A of FIG. 3.

FIG. 4 is another perspective view of the device of FIG. 1.

FIG. 4A is a close-up view of detail A of FIG. 4 showing the plug loaded into the device.

FIG. 4B is a close-up view of detail A of FIG. 4 showing the plug halfway deployed.

FIG. 4C is a close-up view of detail A of FIG. 4 showing the plug fully deployed.

FIG. 5 is an illustration of the method of operation of the device of FIG. 1.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

Turning now to FIGS. 1-5, a device 10 for delivering a nephrostomy plug to a kidney is provided. The device 10 is configured to receive, enclose, and deliver a small plug to be inserted into the kidney to close a nephrostomy tract left in a patient after a PCNL procedure. The device 10 is also con-

figured to allow the user to deploy the plug in a stepwise fashion to control the location and rate of deployment. The device **10** further is configured to be operated in conjunction with a nephroscope using direct vision or fluoroscopy.

Referring to FIG. 1, the device **10** includes an elongate sheath **20** that may be slidably disposed over a push rod **30** (shown in FIG. 2). The sheath **20** may be an elongated tube made of a moldable plastic material such as polyethylene terephthalate (PET). In a preferred embodiment, the sheath **20** may have an outer diameter of about 12 Fr (4 mm), an inner diameter of about 10.6 Fr (3.53 mm), and a working length of about 37 cm. The diameter of the sheath **20** is designed to be compatible with the typical 12-Fr (4 mm) working channel of a nephroscope. The push rod **30** may be a solid thin cylindrical bar made of 304 SS stainless steel or similar, for example. In a preferred embodiment, the push rod **30** may have a working length of about 34.5 cm and a diameter of about 3.175 mm.

The device **10** also includes a handle **50** as shown in FIG. 1. The handle **50** may be ergonomically designed to make the device intuitive and comfortable to use through a nephroscope. The handle **50** may be made of molded acrylonitrile butadiene styrene (ABS) plastic or similar moldable plastic materials. The handle may include a bottom handle half **52** and a top handle half **54**. The handle **50** may enclose a transmission mechanism **60**, as shown in FIG. 2. The handle may also include a push-button **70**.

Referring to FIG. 2A, the transmission mechanism **60** may include a bottom spur gear **62**, a top spur gear **64**, a bottom rack gear **66**, and a top rack gear **68**. The spur gears **62**, **64**, rack gears **66**, **68** and push-button **70** may be made of molded polyethylene terephthalate glycol (PETG) plastic or similar moldable plastic materials.

In one embodiment, the sheath **20** may be coupled to bottom rack gear **66** as shown in FIG. 2A. The sheath **20** may be extruded and then insert molded into bottom rack gear **66**, for example. Bottom rack gear **66** may then be placed on the bottom handle half **52**. The top rack gear **68** may be coupled to the push button **70** and also placed on the bottom handle half **52**. A spring **72** may be inserted into the push button **70** and coupled to a pin **74**, the pin **74** coupling the push button **70** to the bottom handle half **52**. The push rod **30** may be inserted into the bottom handle **52** and fixed to it by, for example, a pin **32**.

A hub or pin **63** may be inserted into the bottom spur gear **62**. The hub **63** may be a stainless steel hub, for example. A roller clutch **65** may be press fit into the top spur gear **64**. Then the spur gears **62**, **64** may be selectively coupled together by inserting the hub **63** into the roller clutch **65**. The bottom spur gear **62** may then be coupled with the bottom rack gear **66**, and the top spur gear **64** may be coupled to the top rack gear **68**, as shown in FIG. 2A. This can also be appreciated with reference to FIGS. 3 and 3A, which show a different perspective (without the handle **50** housing) of the transmission mechanism **60** coupled to the sheath **20** and the push-button **70**.

FIG. 4 illustrates the device **10** loaded with a nephrostomy plug **80** at the distal end **22** of the sheath **20**. In some embodiments, the nephrostomy plug **80** may be made of collagenous extracellular matrix (ECM) or other collagenous materials that have been subjected to processes that expand the materials. Suitable collagenous or ECM materials can be prepared, for example, as described in U.S. Patent Publication No. 20090326577, published Dec. 31, 2009, and U.S. Patent Publication 2009/0318934, published Dec. 24, 2009, hereby incorporated by reference in their entirety. Expanded remodelable collagenous materials can be provided in any suitable

form, including a flowable aqueous composition (e.g., a fluidized composition), a powder, a gel, a sponge, foam, one or more sheets, or a cast body.

In certain forms, such expanded materials can be formed by the controlled contact of an ECM material with one or more alkaline substances until the material expands, and the isolation of the expanded material. Any suitable alkaline substance generally known in the art can be used in this regard. Suitable alkaline substances can include, for example, salts or other compounds that provide hydroxide ions in an aqueous medium. Preferably, the alkaline substance comprises sodium hydroxide (NaOH). Illustratively, the contacting with an alkaline substance can be sufficient to expand the ECM material to at least 120% of (i.e. 1.2 times) its original bulk volume, or in some forms to at least about two times its original volume. Thereafter, the expanded material can optionally be isolated from the alkaline medium, e.g. by neutralization and/or rinsing. The collected, expanded material can be used in any suitable manner in the preparation of a graft device. Illustratively, the expanded material can be enriched with bioactive components, dried, and/or molded, etc., in the formation of a graft construct of a desired shape or configuration. In certain embodiments, a dried construct formed with the expanded ECM material can be highly compressible (or expandable) such that the material can be compressed for delivery, such as from within the lumen of a cannulated delivery device, and thereafter expand upon deployment from the device, for example, so as to become anchored within a patient or otherwise occupy a space within a patient such as when closing or filling an opening or passageway in the patient.

Alkaline treatment of the material can cause changes in the physical structure of the material that in turn cause it to expand. Such changes may include denaturation of the collagen in the material. Denaturation of the collagen matrix of the material can be observed as a change in the collagen packing characteristics of the material, for example a substantial disruption of a tightly bound collagenous network of the starting material. Consequently, an expanded collagenous material typically appears more porous than a corresponding non-expanded collagenous material. The more foamy and porous structure of an expanded ECM or other collagenous material can allow the material to be cast or otherwise prepared into a variety of sponge or foam shapes for use in the preparation of medical materials and devices. It can further allow for the preparation of constructs that are highly compressible and which expand after compression. Such properties can be useful, for example, in preparing the plug to be compressed and loaded into the delivery device described herein. Thus in some embodiments, a plug **80** of cylindrical shape may be used in conjunction with the device **10**. In a preferred embodiment, the plug **80** may have a circular cross-section of about 0.2 inches, and a length of about 0.8-0.9 inches. Once within the body, the plug **80** may hydrate and expand to a size of about 0.6-0.7 inches in diameter in order to fill a nephrostomy tract in the kidney caused by the percutaneous nephrolithotomy procedure.

A starting ECM material (i.e. prior to treatment with the alkaline substance) can optionally include a variety of bioactive or other non-collagenous components including, for example, growth factors, glycoproteins, glycosaminoglycans, proteoglycans, nucleic acids, and lipids. Treating the material with an alkaline substance may reduce the quantity of one, some or all of such non-collagenous components contained within the material. In some instances, one or more bioactive components, exogenous or endogenous, for example, similar to those removed from an expanded material

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during alkaline processing, can be returned to the material. For example, an expanded material can include a collagenous material which has been depleted of nucleic acids and lipids, but which has been replenished with growth factors, glycoproteins, glycosaminoglycans, and/or proteoglycans. These bioactive components can be returned to the material by any suitable method. For instance, in certain forms a tissue extract, such as is discussed in U.S. Pat. No. 6,375,989 which is hereby incorporated by reference in its entirety, containing these components can be prepared and applied to an expanded collagenous material. Other means for returning or introducing bioactive components to an expanded remodelable collagenous material include spraying, impregnating, dipping, etc. as known in the art.

In addition or as an alternative to the inclusion of native bioactive components, such as those provided in a submucosa or other ECM extract, non-native bioactive components including those synthetically produced by recombinant technology or other methods, may be incorporated into the expanded remodelable collagenous material. These non-native bioactive components may be naturally-derived or recombinantly produced proteins that correspond to those natively occurring in the ECM tissue, but perhaps of a different species (e.g. human proteins applied to collagenous ECMs from other animals, such as pigs). The non-native bioactive components may also be drug substances. Illustrative drug substances that may be incorporated into and/or onto the expanded remodelable collagenous materials include, for example, antibiotics, thrombus-promoting substances such as blood clotting factors, e.g. thrombin, fibrinogen, and the like. As with the bioactive components previously described, these substances may be applied to the expanded remodelable collagenous material as a premanufactured step, immediately prior to the procedure (e.g. by soaking the material in a solution containing a suitable antibiotic such as cefazolin), or during or after engraftment of the material in the patient.

FIGS. 4 and 4A illustrate the device 10 loaded with the plug 80. To operate the device 10, the user may insert the distal tip 22 of the device 10 through the working channel of a nephroscope that has already been inserted into the patient's kidney during a PCNL procedure. The device 10 may be operated in conjunction with a nephroscope using direct vision or fluoroscopy. The sheath 20 may include a radiopaque band 24 at its distal end 22 as shown in FIGS. 4A-4C. The radiopaque band 24 may help to identify the precise location of the sheath's distal end 22 for positioning accuracy.

Once the device 10 is in position, the user may depress the push-button 70 once. The depression of the push-button 70 may cause a translational movement of the top rack gear 68 in direction Z, as illustrated in FIG. 2A. The movement of rack gear 68 may in turn cause the spur gears 62, 64 to rotate in direction Y, which results in a translational movement of rack gear 66 in direction X. The movement of rack gear 66 in direction X may thus urge a corresponding retraction of sheath 20 in the same direction. Since the push rod 30 remains in a fixed position relative to the handle 50, the retraction of the sheath 20 may cause a partial exposure of the plug 80. In some embodiments, one depression of the push-button 70 may cause about half the plug 80 to be exposed, as illustrated in FIG. 4B. The portion of the plug 80 deployed halfway may expand in size within the kidney as a result of hydration.

Next the user may withdraw pressure on the push-button 70. The spring 72 may cause the push-button 70 to return to its original position after pressure has been withdrawn. As a result of the push-button 70 returning to its original unde-
pressed position, the top rack gear 68 may move in direction

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W, causing rotation of top spur gear 64 in direction V. The bottom spur gear 62 however may remain in position as a result of the roller clutch 65 preventing transmission of rotation from the top spur gear 64 along with the rotation of the lower spur gear 62 in the V direction. This, in turn, ensures that the sheath 20 remains retracted relative to the push rod 30 as the push-button 70 returns to its original unde-
pressed position.

The user next may depress the push-button 70 once again, repeating the translational motion of the top rack gear 68, which may cause both the top spur gear 64 and the bottom spur gear 62 to rotate in direction x. This, in turn, may cause the bottom rack gear 66 to further move in direction b, which may cause the sheath 20 to further retract in direction b relative to the handle 50 and push rod 30. As a result, the plug 80 may be further exposed as illustrated in FIG. 4C. In some embodiments, a further exposure of plug 80 may also result in full release of the plug into the body of the patient. The plug 80 may then be able to expand to full size due to hydration, providing a seal of the nephrostomy tract on the kidney. FIG. 5 illustrates one embodiment of device 10 inserted into a patient's kidney after plug 80 is fully released into the kidney to provide a seal. It may be appreciated that, in other embodiments, the second depression of the push-button 70 causes only an additional partial deployment of the plug 80. The total deployment of the plug 80 may occur at the end of a total of three, or more, depressions of the push-button 70.

It should be appreciated that the device 10 may be operated using a single hand, thus freeing the user to manipulate any other instrument with the other hand. In addition, the handle 50 may be ergonomically designed for intuitive use and comfort. In addition, the stepwise advancement or exposure of the plug permits the user to control the location and the rate of deployment for effectively.

While the preferred embodiments of the disclosure have been described, it should be understood that the disclosure is not so limited and modifications may be made without departing from the disclosure. The scope of the invention is defined by the appended claims, and all devices that come within the meaning of the claims, either literally or by equivalence, are intended to be embraced therein.

The invention claimed is:

1. A medical device, comprising:

a tubular member having a proximal end and a distal end, the tubular member configured for insertion into a biological body;

a handle coupled to the proximal end of the tubular member, the handle comprising:

a pusher element configured to slide within the tubular member to deliver a plug through the distal end of the tubular member;

an actuation element comprising:

a button; and

a spring coupled to the button;

a transmission coupled to the tubular member and the actuation element, the transmission comprising:

a first rack coupled to the button;

a second rack coupled to tubular member;

a first gear engaged with the first rack;

a second gear engaged with the second rack, the second gear selectively coupled to the first gear; and
a roller clutch coupled to the first gear;

wherein a first depression of the button urges a first rotation of the first and second gears in a first direction, causing a retraction of the tubular member relative to the pusher element;

wherein upon a release of the button the first gear rotates in a direction opposite the first direction but the second gear remains stationary; and

wherein a second depression of the button urges a second rotation of the first and second gears in the first direction, 5
causing a further retraction of the tubular member relative to the pusher element.

2. The medical device of claim 1, wherein the pusher element is a cylindrical rod.

3. The medical device of claim 1, further comprising the 10
plug disposed within the tubular member at the distal end of the tubular member.

4. The medical device of claim 3, wherein the plug has a cylindrical shape.

* * * * *